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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,633	04/09/2004	Zia Yassinzadeh	021872-001900US	9024

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EXAMINER
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DANG, PHONG SON H

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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03/17/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@kilpatricktownsend.com  
ipefiling@kilpatricktownsend.com  
jlhice@kilpatrick.foundationip.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,633	<b>Applicant(s)</b> YASSINZADEH, ZIA	
	<b>Examiner</b> SON DANG	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-11,14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-11,14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/11/2011</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The amendment filed 12/30/2010 has been entered. The previous 35 USC 112 rejections to claims 7-11 have been withdrawn in light of applicant amendment to claims 7-11. Claims 2, 6, 12-13, 15-16 and 22-67 remain cancelled. Claims 1, 3-5, 7-11, 14 and 17-21 are pending in the application.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-5, 7-11, 14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recited "wherein the compression element is not in direct contact with the vessel wall..." This limitation has not been recited in the specification.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5, 8-11, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,419,765 to Weldon et al. (Weldon) in view of US Patent No. 7,621,936 to Cragg et al. (Cragg).

In Regards to claims 1, 5, 8-11, 17 and 20:

Weldon teaches:

A method for hemostasis of a puncture site in a wall of a blood vessel at an end of a tissue tract having a sheath (10, Fig. 22A) therein, the method comprising: providing a locating member (120, Fig. 22B) having a proximal end, a distal end, and an expansible member (124, Fig. 22B) disposed on the distal end thereof, inserting the locating member (120, Fig. 22B) through the sheath (10, Fig. 22B) in the tissue tract so that the expansible member (124, Fig. 22C) on the locating member (120, Fig. 22C) enters a lumen of the blood vessel; expanding the expansible member (124, Fig. 22C) on the inserted locating member (120, Fig. 22C) and drawing the inserted locating member (120, Fig. 22C) proximally so that the expanded expansible member (124, Fig. 22C) covers the puncture site in the vessel wall; removing the sheath (Fig. 22C) from the tissue tract while the inserted locating member (120, Fig. 22C) remains in place; providing a tubular compression member (56, Fig. 24A) having a proximal end, a distal end, a central passage (126, Fig. 22D) between said proximal end and said distal end, and an expansible tissue compression element (64, Fig. 24A) disposed over the distal portion thereof, and advancing the tubular compression member (56, Fig. 24A) over the inserted locating member (120, Fig. 24A) after

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the sheath (10, Fig. 22A) has been removed from the tissue tract so that the locating member (120, Fig. 22D) is received in the central passage (126, Fig. 22D) of the tubular compression member (56, Fig. 24A) and the distal end of the expansible tissue compression element (64, Fig. 24D) is located within the tissue tract at a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region (Fig. 24D); and expanding the expansible tissue compression element (64, Fig. 24C) within the tissue tract above the blood vessel wall to apply pressure against subcutaneous tissue and to compress said tissue over the puncture site in the blood vessel wall (The membrane 64 is compressing over the predetermined space which the hemostasis material is occupied) to promote hemostasis, wherein the expansible tissue compression element (64, Fig. 24C) on the compression member (56, Fig. 24C) is left in place until hemostasis has been achieved. The expansible element being a balloon (124, Fig. 22C). Inflating a distal face of the balloon at an angle to the compression member, expanding comprises inflating the balloon (32, Fig. 22F) to a deployed configuration comprising a conical shape, unfolding concentric folds of the balloon (membrane 64 is folded in Fig. 24A before being unfold/inflate in Fig. 24C), inflating the balloon (64, Fig. 24C) to a deployed configuration having a concave distal end (Fig. 22F). Contracting and withdrawing the locating member (120, Fig. 22B) while the compression member (56, Fig. 24A) remains in place (Col. 14, lines 26-28). Delivering a clot promoting agent (65, Fig. 24B) or anti-infection agent to the puncture site.

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Weldon fails to teach:

The compression element is not in direct contact with the vessel wall.

Cragg teaches:

The compression element (pusher 80, Fig. 1c) is not in direct contact with the vessel wall (Fig. 1c)

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate more of the hemostatic material into the tissue tract in order to better assist in promotion for hemostasis in the case some of the hemostasis material fall in to the lumen of the blood vessel before the hemostasis process begins. Hence, with the bigger amount of hemostasis material being put into the tissue tract, the compression element would not in direct contact with the vessel wall.

6. Claims 3-4, 7, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon in view of Cragg. Weldon discloses the claimed invention except for disclosing the predetermined distance is in a range from about 0.05 inch to about 0.5 inch or 0.2 inch to about 0.3 inch and the expansible diameter member on the locating member is expanded to an expanded configuration within the blood vessel having a diameter in range from about 0.05 inch to about 0.5 inch. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the predetermine distance in a range from 0.05 inch to about 0.5 inch or 0.2 inch to about 0.3 inch and the expansible diameter member on the locating member is expanded to an expanded configuration within the blood vessel having a diameter in range from about 0.05 inch to about 0.5 inch, since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Weldon fails to disclose the step of inflating a superior aspect of the balloon greater than inferior aspect of the balloon. It is obvious to one of ordinary skill in the art at the time of the invention to modify/change in form/shape of the of the balloon as it is well known in the art as In re Dailey, 149 USPQ 47 (CCPA 1966).

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon in view of Cragg and further in view of US Patent No. 5,690,674 to Diaz.

In regards to claim 18:

Weldon in view of Cragg teaches:

The method of claim 1 (See rejection of claim 1 above).

Weldon in view of Cragg fails to teach:

Imaging the expansible element during positioning.

Diaz teaches:

Imaging the expansible element during positioning (Col. 4, lines 24-31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ an imaging device to monitor the position of the implant or device within the body.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon in view of Cragg and further in view of US Patent No. 5,507,744 to Tay et al. (Tay).

In regards to claim 19:

Weldon in view of Cragg teaches:

The method of claim 1 (see rejection of claim 1 above).

Weldon in view of Cragg fails to teach:

Delivering radio frequency energy, ultrasound energy, or microwave energy to the puncture site.

Tay teaches:

Delivering radio frequency energy, ultrasound energy, or microwave energy to the puncture site (Col. 2, lines 42-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilized radio frequency energy to help closing and sealing a puncture at a puncture site as it is well known in the art for substituting one known method for another that would yield expected results.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon in view of Cragg and further in view of US PG PUB No. 2003/0100920 to Akin et al. (Akin).

In regards to claim 21:

Weldon in view of Cragg teaches:

A compression member (56, Fig. 24A).

Weldon in view of Cragg fails to teach:

Instructions to use the compression member for hemostasis of a puncture site in a blood vessel.

Akin teaches:

Instruction to use the device.



It would have been obvious to one of ordinary skill in the art at the time of the invention to provide instructions on how to use the device of Weldon in view of Cragg in order to allow a user to properly use the device

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1, 3-5, 7-11, 14 and 17-21 have been considered but are moot in view of the new ground(s) of rejection. Claims 1, 3-5, 7-11, 14 and 17 are also rejected over new matter. The method step in claim 1 recites a predetermined distance 106 shows in Fig. 8D but after the steps of expanding the compression element and pushing compression element toward the vessel wall for compression showing in Figs. 8E-F, the predetermined distance has decreased in distance, another word, the predetermined distance is not there anymore and the step of "the compression element is not in direct contact with the vessel wall..." is an addition and that step has not been recited in the specification; therefore, that limitation is a new matter.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/S. D./  
Examiner, Art Unit 3773

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Primary Examiner, Art Unit 3773